

B3

--24. (Amended) The composition of Claim 11 in the form of a tablet, capsule, granulate, or a powder.--

Please add new Claim 31:

B4

--31. (New) A vial comprising the composition of Claim 11.--

### REMARKS

Claims 11-18 and 20-31 are pending. As suggested by the Examiner, the Applicants provide herewith a Declaration Under 37 C.F.R. §1.132 showing the superior results obtained by the combination of acetyl-L-carnitine and hydroxycitric acid of the present invention. These experimental data show the superior, surprising and synergistic effects of the combination of acetyl-L-carnitine and hydroxycitric acid on triglyceride and cholesterol levels. Other editorial changes have been made to Claims 12-14, 18, 20 and 24 to improve their clarity or for consistency with independent Claim 11 as amended. Support for new Claim 31 is found in original Claim 9. Accordingly, the Applicants do not believe that any new matter has been introduced.

### Rejection--35 U.S.C. 112, second paragraph

Claims 16, 18, 21, 23, 24 and 26 were rejected under 35 U.S.C. 112, second paragraph as being indefinite.

Claim 18 has been amended to recite that the natural product or extract of Claim 16 is obtained from "a" fruit so as not to imply an antecedent basis in Claim 16 for the term "fruit".

Claim 21 refers to "vegetal fiber". This term refers to fiber from a plant.

Claim 23 refers to "semisolid" or "semiliquid" compositions. Such compositions may contain a solid or liquid component in combination with another non-solid or non-liquid

component, respectively. These terms also refer to compositions having intermediate properties, especially in rigidity, between solids and liquids, e.g. gels.

Claim 24 has been amended to delete the term “vial”. This term now appears in Claim 31.

Claim 26 refers to “facilitating the metabolism of lipids”. This term encompasses the modulation of lipid metabolism, for instance, as described in the disclosure, page 8, lines 6-12.

In view of the above comments and explanations, the Applicants respectfully request that the indefiniteness rejections now be withdrawn.

#### Rejection--Double Patenting

Claim 30 was rejected under the judicially-created doctrine of double patenting over claims 1-15 of U.S. Patent No. 6,217,898. The claims of the prior patent recite propionyl-L-carnitine. Applicants submit that this rejection no longer applies in view of the limitation of the present claims to compositions comprising acetyl-L-carnitine.

#### Rejection--35 U.S.C. 102

Claims 11-15, 19-21 and 23-27 were rejected under 35 U.S.C. 102(b) as being anticipated by Wiegand, U.S. Patent 3,810,994 or Burtle, U.S. Patent 5,030,657.

The claims have been amended and no longer recite pantothenic acid, accordingly the Applicants submit that Wiegand or Burtle are no longer applicable, as these documents disclose the combination of carnitine and pantothenic acid, but not the combination of acetyl-L-carnitine and hydroxycitric acid. See, e.g., Wiegand, col. 3, lines 26-42 and Burtle, col. 5 (Table 1) and col.7 (Table 2). Moreover, these documents do not suggest combining HCA with acetyl-L-carnitine nor do they disclose the superior, synergistic effects of this combination on triglyceride and cholesterol levels as shown by the attached declaration.

Rejection--35 U.S.C. 103

Claims 11-30 were rejected under 35 U.S.C. 103(a) as being unpatentable over Wiegand, U.S. Patent 3,810,994 by itself, or further in view of Moffett, U.S. Patent 5,536,516.

The cited prior art does not render the present invention obvious, as there is no suggestion in the prior art to specifically combine acetyl-L-carnitine and hydroxycitric acid ("HCA"). Wiegand is directed the combination of carnitine and pantothenic acid, but not the combination of acetyl-L-carnitine and hydroxycitric acid. Thus, Wiegand by itself does not disclose all the elements of the present invention or suggest combining HCA with acetyl-L-carnitine.

Moffett is directed to hydroxycitric acid from Garcinia rind, but does not suggest combining HCA with acetyl-L-carnitine, nor disclose the superior, synergistic effects of this combination on triglyceride and cholesterol levels as shown by the attached declaration. As shown in this declaration, the combination of acetyl-L-carnitine and HCA provides superior and highly significant reductions in body weight, triglycerides and cholesterol compared to either acetyl-L-carnitine alone or HCA alone, see Tables 2, 4 and 5. Synergy is shown as the sum of the effects of the inventive combination of HCA and acetyl-L-carnitine are greater than the effects of either of these two ingredients alone. Accordingly, as the cited prior art does not suggest the present invention or the superior properties of the present invention, the Applicants respectfully request that this rejection be withdrawn.

Rejection--35 U.S.C. 103

Claims 11-15, 19-20 and 22-30 were rejected under 35 U.S.C. 103(a) as being unpatentable over Wiegand, U.S. Patent 3,810,994, in view of Leung, U.S. Patent 5,039,698.

Independent Claim 11 has been amended and no longer recites the term “panthothenic acid”. Accordingly, the Applicants submit that this rejection may be withdrawn as neither document discloses or suggests the combination of acetyl-L-carnitine with hydroxycitric acid.

#### Rejection--35 U.S.C. 103

Claims 11-30 were rejected under 35 U.S.C. 103(a) as being unpatentable over Hastings, U.S. Patent 5,626,849 by itself, or in view of Wiegand, U.S. Patent 3,810,994 or Burtle, U.S. Patent 5,030,657, or both.

The cited documents do not render the present invention obvious because they do not suggest the combination of acetyl-L-carnitine and HCA or suggest the superior and surprising properties of this combination.

Hastings discloses HCA as one ingredient in a weight loss composition and that HCA reduces the synthesis of fats, see col. 2, lines 24-29. Carnitine is also disclosed as one type of ingredient which may be used in a weight loss composition, see col. 3, lines 40-45. Hastings by itself does not suggest using acetyl-L-carnitine. Moreover, there is no suggestion to combine acetyl-L-carnitine with HCA or the superior properties of this combination. For example, Hastings does not suggest the present invention or the superior and synergistic properties of the combination of HCA and acetyl-L-carnitine on reducing body weight, and levels of triglycerides and cholesterol, see Tables 2, 4 and 5 of the attached Declaration. Similarly, as discussed above, neither Wiegand nor Burtle suggest the combination of HCA and acetyl-L-carnitine or the superior, synergistic properties of this combination.

Accordingly, as none of the cited prior art suggests specifically combining acetyl-L-carnitine with HCA, nor does it suggests the superior, synergistic properties of this combination, the Applicants respectfully request that this rejection be withdrawn.

#### Rejection--35 U.S.C. 103

Claim 18 was rejected under 35 U.S.C. 103(a) as being unpatentable over Hastings, U.S. Patent 5,626,849 by itself, or in view of Wiegand, U.S. Patent 3,810,994 or Burtle, U.S. Patent 5,030,657, or both, and further in view of page 4 of the specification. Page 4 of the specification was cited for its teaching that HCA may be obtained from certain plant sources. However, as the cited prior art references do not suggest the basic combination of acetyl-L-carnitine and HCA for the reasons set forth above with respect to Claims 11-30, the Applicants submit that Claim 18 is also not obvious.

#### Rejection--35 U.S.C. 103

Claim 23 was rejected under 35 U.S.C. 103(a) as being unpatentable over Hastings, U.S. Patent 5,626,849 by itself, or in view of Wiegand, U.S. Patent 3,810,994 or Burtle, U.S. Patent 5,030,657, or both, and further in view of Weiner (1989) by itself, or in combination with Stracher, U.S. Patent 5,008,288. The Applicants submit that Claim 23 is not obvious for the reasons set forth above with respect to Claims 11-30. Weiner is cited for teachings of liposomes as drug delivery agents and Stracher as teaching carnitine incorporation into liposomes. The compositions comprising acetyl-L-carnitine and HCA are not obvious for the reasons set forth above--there is no motivation to combine acetyl-L-carnitine and HCA or any suggestion of the superior properties of this combination. As the basic combination of acetyl-L-carnitine and HCA of the present invention is not obvious for the reasons set forth above, then liposomes comprising this combination would also not be obvious.

#### Rejection--35 U.S.C. 103

Claims 28-30 were rejected under 35 U.S.C. 103(a) as being unpatentable over Wiegand, U.S. Patent 3,810,994 or Burtle, U.S. Patent 5,030,657; or Wiegand, U.S. Patent 3,810,994, in view of Moffett, U.S. Patent 5,536,516; or Hastings, U.S. Patent 5,626,849 by itself, or in view of Wiegand and/or Burtle, and further in view of Cavazza, U.S. Patent 4,268,524.

Wiegand, Burtle, Moffett and Hastings have been addressed above. Briefly, these documents do not disclose or suggest compositions comprising acetyl-L-carnitine and HCA or suggest the superior, synergistic properties of this combination.

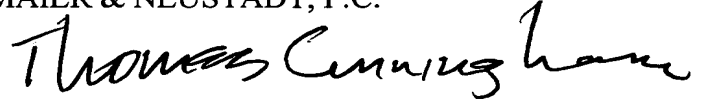
Cavazza is generally directed to a method of using acylcarnitines to increase levels of high-density lipoproteins. While Table 4 of Cavazza indicates the effects of acylcarnitines on serum lipids, it does not disclose or suggest the surprising, superior and synergistic properties of the combination of acetyl-L-carnitine and HCA. As shown in Tables 4 and 5 of the attached Declaration this combination provides highly significant reductions in triglycerides and cholesterol levels compared to acetyl-L-carnitine alone or HCA alone. The superior and synergistic effects of the combination of acetyl-L-carnitine and HCA are not suggested by Cavazza or the other cited art. Accordingly, the Applicants respectfully request that this ground of rejection also be withdrawn.

## CONCLUSION

In view of the above amendments and remarks, the Applicants respectfully submit that Claims 11-18 and 20-31 are now in condition for allowance. Early notification to that effect is earnestly solicited.

Respectfully submitted,

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Attachment: Declaration Under 37 C.F.R. §1.132 (6 pp. - Executed Original)

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Amendment Filed: **01/02/02**

**IN THE CLAIMS**

Please cancel Claim 19.

Please amend Claims 11-15, 18, 20 and 24 as follows:

--11. (Amended) A composition comprising:

- (i) a first component selected from the group consisting of [C<sub>2</sub>-C<sub>8</sub>-alkanoyl] acetyl L-carnitine, [and] a salt[s] thereof [C<sub>2</sub>-C<sub>8</sub>-alkanoyl L-carnitine] and an ester thereof; and
- (ii) a second component selected from the group consisting of a hydroxycitric acid[,]  
and a hydroxycitric acid derivative[, pantothenic acid, and a pantothenic acid derivative].

12. (Amended) The composition of Claim 11[, wherein the alkanoyl group of the first component is selected from the group consisting of acetyl, propionyl, butyryl, valeryl and isovaleryl] that comprises acetyl-L-carnitine.

13. (Amended) The composition of Claim 11[, wherein the first component is acetyl-L-carnitine] that comprises a derivative of acetyl-L-carnitine.

14. (Amended) The composition of Claim 11[, wherein the first component is propionyl-L-carnitine,] that comprises hydroxycitric acid or a salt or ester thereof.

15. (Amended) The composition of Claim [14] 11[, wherein said] that comprises a pharmaceutically acceptable salt of [propionyl] acetyl L-carnitine [is] selected from the group consisting of [propionyl] acetyl L-carnitine chloride, [propionyl] acetyl L-carnitine bromide, [propionyl] acetyl L-carnitine orotate, [propionyl] acetyl L-carnitine acid aspartate, [propionyl] acetyl L-carnitine acid phosphate, [propionyl] acetyl L-carnitine fumarate,



[propionyl] acetyl L-carnitine lactate, [propionyl] acetyl L-carnitine maleate, [propionyl] acetyl L-carnitine acid maleate, [propionyl] acetyl L-carnitine acid oxalate, [propionyl] acetyl L-carnitine acid sulfate, [propionyl] acetyl L-carnitine glucose phosphate, [propionyl] acetyl L-carnitine tartrate, and [propionyl] acetyl L-carnitine acid tartrate.

16. (Amended) The composition of Claim 11, [wherein the second component is] that comprises a second component selected from the group consisting of hydroxycitric acid, a salt of hydroxycitric acid, an ester of hydroxycitric acid, and a natural product or extract containing hydroxycitric acid or a salt or ester thereof.

17. (Amended) The composition of Claim 11[, wherein the] that comprises a second component that is calcium hydroxycitrate.

18. (Amended) The composition of Claim 16[, wherein said] that comprises a natural product or extract [is] obtained from a fruit selected from the group consisting of Garcinia, Malabar Tamarind and gorikapuli.--

--20. (Amended) The composition of Claim 11, wherein the weight ratio of the second component to the first component is:

1:1 to 1:100[, when the second component is hydroxycitric acid or a derivative thereof, and

10:1 to 1:100, when the second component is pantothenic acid or a derivative thereof].--

--24. (Amended) The composition of Claim 11 in the form of a tablet, capsule, granulate, or a powder [or as contained within a vial suitable for oral, parenteral, rectal or topical administration].--

Please add new Claim 31:

--31. (New).--

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